Great Britain Prescribing Information:

SCEMBLIX®▼ (asciminib) 20 mg and 40mg film-coated tablets

Important note: Before prescribing, consult Summary of Product Characteristics (SmPC).
Presentation: Each film-coated tablet contains asciminib hydrochloride, equivalent to 20mg and 40mg asciminib respectively. Contains Lactose.
Indication(s): Scemblix is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph + CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors, and without a known T315I mutation.
Dosage and administration: The recommended total daily dose is 80 mg; taken orally without food, either as 80 mg once daily at the same time each day or as 40 mg twice daily at approximately 12-hour intervals. Tablets should be swallowed whole and food consumption should be avoided for at least 2 hours before and 1 hour after taking asciminib. Treatment should be continued as long as clinical benefit is observed or until unacceptable toxicity occurs. For 80 mg once-daily dosage regimen: If a dose is missed by more than approximately 12 hours, it should be skipped and the next dose should be taken as scheduled. For 40 mg twice-daily dosage regimen: If a dose is missed by more than approximately 6 hours, it should be skipped and the next dose should be taken as scheduled. *Dose modification:* For the management of adverse reactions, the dose can be reduced based on individual safety and tolerability (See Warnings & Precautions). For 80 mg once-daily dosage regimen, dose reduce to 40 mg once daily. For 40 mg twice-daily dosage regimen, dose reduce to 20 mg twice daily. Refer to the SmPC for management of selected adverse reactions. *Renal impairment:* No dose adjustment is required in patients with mild, moderate or severe renal impairment. *Hepatic impairment:* No dose adjustment is required in patients with mild, moderate or severe hepatic impairment. No data available in patients with moderate or severe hepatic impairment, caution should be exercised in these patients. *Paediatric population:* Safety and efficacy in paediatric patients aged below 18 years have not been established. No data are available. *Elderly:* No dose adjustment is required in patients aged 65 years or above.
Contraindications: Hypersensitivity to the active substance or to any excipients.
Warnings/Precautions: *Myelosuppression:* Treatment is associated with thrombocytopenia, neutropenia and anaemia with severe (NCI CTCAE grade 3 or 4) thrombocytopenia and neutropenia events reported during treatment. Complete blood counts should be performed every two weeks for the first 3 months of treatment and then monthly thereafter. Patients should be monitored for signs and symptoms of myelosuppression. *Pancreatic toxicity:* Patients should be monitored for signs and symptoms of pancreatic toxicity. Serum lipase and amylase levels should be assessed monthly during treatment or as clinically indicated. More frequent monitoring should be performed in patients with a history of pancreatitis. If serum lipase and amylase elevation are accompanied by abdominal symptoms, treatment should be temporarily withheld and appropriate diagnostic tests should be considered to exclude pancreatitis. *QT prolongation:* It is recommended that an electrocardiogram is performed prior to the start of treatment and monitored during treatment as clinically indicated. Hypokalaemia and hypomagnesaemia should be corrected prior to asciminib administration and monitored during treatment as clinically indicated. Caution should be exercised when administering asciminib concomitantly with medicinal products known to cause torsades de pointes or in patients who have a history of or predisposition for QTc prolongation or uncontrolled or significant cardiac disease including bradycardia. *Hypertension:* Hypertension should be monitored and managed using standard antihypertensive therapy during treatment with asciminib as clinically indicated. *Hepatitis B reactivation:* Reactivation of hepatitis B virus (HBV) has occurred in patients who are chronic carriers of this virus following administration of other BCR::ABL1 tyrosine kinase inhibitors (TKIs). Patients should be tested for HBV infection before the start of treatment with asciminib. HBV carriers should be closely monitored for signs and symptoms of active HBV infection throughout therapy and for several months following termination of therapy. *Lactose:* Scemblix tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Interactions: Caution should be exercised during concomitant administration of the following, where dose adjustment of asciminib is not required:
• Strong CYP3A4 inducers, including carbamazepine, phenobarbital, phenytoin or St. John's wort (Hypericum perforatum).
• CYP3A4 substrates known to have a narrow therapeutic index, including fentanyl, alfentanil, dihydroergotamine or ergotamine.
• CYP2C9 substrates known to have a narrow therapeutic index, including, phenytoin or warfarin.
• P-gp substrates known to have a narrow therapeutic index including but not limited to digoxin, dabigatran and colchicine. A drug that is a substrate of P-gp may result in a clinically relevant increase in the plasma concentrations of P-gp substrates, where minimal concentration changes may lead to serious toxicities.
• Medicinal products with a known risk of torsades de pointes, including, bepridil, chloroquine, clarithromycin, halofantrine, haloperidol, methadone, moxifloxacin or pimozide.
• Hydroxypropyl-β-cyclodextrin containing oral products. The bioavailability of asciminib decreases on consumption of food.
Fertility, pregnancy and lactation: Asciminib is not recommended for use during pregnancy, or in women of childbearing potential not using contraception. The patient should be advised of a potential risk to the foetus if asciminib is used during pregnancy or if the patient becomes pregnant while taking asciminib. Breast-feeding is not recommended during treatment and for at least 3 days after stopping treatment with asciminib. There is no data on the effect of asciminib on human fertility.
Undesirable effects: *Very common (≥1/10):* Upper respiratory tract infection, thrombocytopenia, neutropenia, anaemia, dyslipidaemia, headache, dizziness, hypertension, dyspnoea, cough, pancreatic enzymes increased, vomiting, diarrhoea, nausea, abdominal pain, hepatic enzyme increased, rash, pruritus, musculoskeletal pain, arthralgia, fatigue, oedema, pyrexia, decrease in phosphate levels. *Common (≥1/100 to <1/10):* Lower respiratory tract infection, influenza, decreased appetite, dry eye, vision blurred, palpitations, pleural effusion, non-cardiac chest pain, pancreatitis, blood bilirubin increased, urticaria, electrocardiogram QT prolonged, blood creatine phosphokinase increased. *Uncommon (≥1/1,000 to <1/100):* Febrile neutropenia, pancytopenia, hypersensitivity. *Other Adverse Effects:* Please consult the Summary of Product Characteristics for a detailed listing of all adverse events before prescribing.
Legal classification: POM
Marketing Authorisation (MA) number, quantities and price:
This product has a GB licence.
PLGB 00101/1207 – 20 mg x 60 tablet pack £4,050.37 PLGB 00101/1208 – 40 mg x 60 tablet pack £4,050.37
Date of last revision of prescribing information: October 2024
Full Prescribing Information available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

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Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report or alternatively email medinfo.uk@novartis.com
or call 01276 698370